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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,644	10/08/2004	Akihiko Mizutani	MIZUTANI3	4955

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EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
04/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,644	MIZUTANI ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-15,17 and 19* is/are pending in the application.

4a) Of the above claim(s) *10-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-9,14, 15, 17, and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' amendment and remarks, which were filed on 5 January 2009.

* * * * *

Election/Restrictions

Applicants request rejoinder of claim 13 with elected Group I following the amendment of 5 January 2009 (*see* remarks, page 7).

Examiner respectfully submits that the restriction requirement of 25 September 2006 was made final in the Office action of 17 January 2007. If applicants wish to claim additional subject matter within the scope of the elected group, they may add new claims. As for claim 13, it was withdrawn from further consideration in the Office action of 17 January 2007.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-9, and 14, 15, 17, and 19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,893,658 ("Iida") in view of U.S. Patent No. 3,784,684 ("Bossert").

Iida discloses a light stable soft capsule formulation (*see* col. 3, lines 7-18) comprising:

- the shell containing a non-water soluble light-shielding agent of instant claim 1 and 19(*see* col. 2, lines 1-7);
- the non-water-soluble light-shielding agent of instant claim 1 and 19 (*see* col. 3, lines 21-23);
- the 200 μm thickness of instant claim 1 (*see* claim 1);
- the medicament encapsulated by the shell of instant claim 1 (*see* col. 2, line 49);
- the titanium oxide of instant claim 3 (*see* col. 3, lines 7-18);
- the seamless shell of instant claim 5 (*see* col. 5, lines 18-40);
- the light-unstable medicament of instant claim 6 (*see* col. 2, line 49);
- the medicament suspended in a liquid base of instant claim 7 (*see* col. 5, line 10);
- the vitamin D derivative of instant claim 8 (*see* col. 2, line 49);
- the gelatin of instant claim 9 (*see* col. 4, line 16)'
- the unit dose of instant claim 14 (see col. 1, lines 5-6);
- the capsule of instant claim 15 (see col. 1, lines 5-6); and
- the non-water-soluble light-shielding agent of instant claim 18 (*see* col. 3, lines 21-23).

Iida differs from the instant application in that it does not disclose the concentration of non-water-soluble light-shielding agent recited in claims 1, 18, and 19.

However, a concentration of non-water-soluble light-shielding agent in a shell of up to 5%, is disclosed in Bossert (*see* col. 3, lines 67-68).

Iida explain that the disclosed formulation is beneficial because it provides "excellent stability to light and heat and good discrimination." *See* col. 2, lines 39-40.

While Iida does not explicitly teach the percentages of instant claims 16 and 17, or the capsule size of instant claim 4, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages and size through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration and size will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage range or size. The prior art discloses a titanium dioxide of up to 5%, as explained above (*see* Bossert; col. 3, lines 67-68).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a light stabilized soft capsule formulation comprising a shaell containing titanium oxide, and a vitamin D derivative encapsulated in the shell, as taught by Iida et al. One of ordinary skill in the art at the time the invention was made

would have been motivated to make such a composition because it results in excellent stability to light and heat and good discrimination, as explained by Iida, et al.

* * * * *

Response to Arguments

Applicants' arguments filed 5 January 2008 have been fully considered but they are not persuasive.

1. Applicants argue, "[i]t should be noted that the amount of 5% of opacifier disclosed in Bossert is intended to prepare a capsule having a standard wall thickness, which may be the same as the commonly used shell thickness, i.e., greater than 200μm up to 600μm, referred to in the present specification. *See* remarks, page 11.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze,346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 2145. Examiner respectfully submits that Bossert does not disclose a shell thickness. Based on the purpose of Bossert's formulation, i.e. instant oral-release, a thinner than standard shell thickness would be preferred. In any event, Bossert has not disclosed a shell thickness.

2. Applicants argue, "[i]t is clear that neither Iida nor Bossert suggest any reduced shell thickness of a capsule..." *See* remarks, page 12.

Examiner respectfully submits that Iida discloses a shell thickness which overlaps with that of instant claim 1, *i.e.* 200μm (*see* col. 4, line 47).

3. Applicants argue that they have amended the non-water-soluble light-shielding agent concentration to 10-25 wt%. *See* remarks, page 12.

"The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . .In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). *See* MPEP 2144.05. Examiner respectfully submits that the instant specification discloses a light-stabilization effect with 5-25 wt% non-water-soluble light-shielding agent (*see* page 19, line 19). As such, applicants do not show criticality or unexpected results between a concentration of 5 wt% and 10 wt%.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 10-13 drawn to an invention nonelected with traverse in the reply filed on 23 October 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615